

Serial No.: 10/054,447

Confirmation No.: 5485

Filed: January 22, 2002

For: METHOD FOR COATING MEDICAL DEVICE SURFACES

Remarks

The Office Action mailed December 4, 2006 has been received and reviewed. Claims 1, 5, and 276 having been amended, claims 52-61, 103-114, 162-173, 234-243, 246-249, 255-261, 264-267, and 282-292 having been canceled herein, and no claims having been added, the pending claims are claims 1-10, 233, and 273-281, all of which are currently under consideration by the Examiner. Applicants reserve the right to prosecute the subject matter of canceled claims 52-61, 103-114, 162-173, 234-243, 246-249, 255-261, 264-267, and 282-292, all of which were withdrawn from consideration by the Examiner as being drawn to non-elected groups, in Divisional and/or Continuation applications.

Claim 1 has been cosmetically amended to explicitly recite that the medical device having the catechol moiety disposed on the surface thereof is coated with the hydrophilic polymer.

Claims 5 and 276 have been amended to delete the language "a polymer comprising a hydrophilic chemical moiety" from the Markush groups recited therein.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-10, 276, and 280-281 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

First, the Examiner alleged that claim 1 is not clear as to whether or not the catechol is disposed on the surface of the device separately from the hydrophilic polymer. Applicants respectfully submit that claim 1, when read in view of the specification, particularly points out and distinctly claims the subject matter which Applicants regard as the invention. However, in the interest of expediting the prosecution of the present application, claim 1 has been amended to recite that the medical device having the catechol moiety disposed on the surface thereof is coated with the hydrophilic polymer, and the rejection has been rendered moot.

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Next, the Examiner alleged that the language “a polymer comprising a hydrophilic chemical moiety” in the Markush groups recited in claims 5 and 76 is not further limiting of a “hydrophilic polymer.” Claims 5 and 76 having been amended to delete the noted language, the rejection has been rendered moot.

Finally, the Examiner alleged that claims 9-10 and 280-281 do not further limit claims 1 and 233, respectively. Applicants respectfully traverse the rejection.

Applicants respectfully submit that claims 9-10 and 280-281 further limit claims 1 and 233, respectively. For example, because neither claim 1 nor claim 233 recite a primer, and claims 9-10 and 280-281 each recite a primer, claims 9-10 and 280-281 further limit claims 1 and 233, respectively.

In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-5, 7, 9-10, 233-276, 278, and 280-281 under 35 U.S.C. §102(b) as being anticipated by Sawhney (U.S. Patent No. 6,818,018 B1). Applicants note that Sawhney issued on November 16, 2004, which is after both the priority date and filing date of the present application. Thus, Sawhney is not available as art against the present application under either 35 U.S.C. §102(a) or (b). However, to the extent that Sawhney might be available as art against the present application under another section of 35 U.S.C. §102, Applicants respectfully traverse the rejection.

Sawhney “relates generally to the in situ formation of hydrogels, and more specifically, to compositions of hydrogels that are formed in situ by a combination of physical and chemical crosslinking” (column 1, lines 5-8). As noted by the Examiner, Sawhney recites “poly(guanidine)” as one example among many of water soluble polymers that can be used to form the hydrogels (column 12, line 21).

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In one embodiment, Sawhney discloses that “[t]he in situ formed hydrogels of the present invention further may be applied in conjunction with bioactive molecules that either are dissolved or dispersed within the hydrogels” (column 15, line 66 to column 16, line 2), and recites “dopamine” as one example among many of suitable biologically active agents (e.g., column 17, line 46).

In another embodiment, Sawhney discloses that “such hydrogels also may be used to coat other types of implants for long-term use in the body, such as catheters, cannulas, bone prostheses, cartilage, replacements, minipumps and other drug delivery devices, artificial organs and blood vessels, meshes for tissue reinforcement, etc. Hydrogel compositions also may be used to coat platinum wires, which then are administered to the site of an aneurysm via catheter. Such surface treatment renders the implants nonimmunogenic and reduces the incidence of foreign body reaction.” (Column 19, lines 27-36).

However, the Examiner has failed to point to, and Applicants’ Representatives have been unable to locate, any specific disclosure by Sawhney of a hydrogel formed from a poly(guanidine) polymer that includes any bioactive agent, much less dopamine. Further, the Examiner has failed to point to, and Applicants’ Representatives have been unable to locate, any specific disclosure by Sawhney of a hydrogel that includes a bioactive agent used to coat a medical device, much less a hydrogel formed from a poly(guanidine) polymer that includes a bioactive agent (and in particular dopamine) used to coat a medical device.

For at least these reasons, the Examiner’s rationale for supporting the rejection, in that “said composition would dispose a catechol on the surface of the device and a chemical bond would form between the catechol and guanidino moiety,” is clearly not supported by the teachings of Sawhney. For at least this reason, Applicants respectfully submit that claims 1-5, 7, 9-10, 233-276, 278, and 280-281 are not anticipated by Sawhney.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

Amendment and Response

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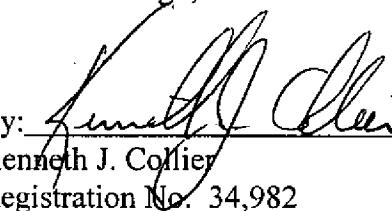
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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for,
James R. Keogh, et al.

March 5, 2007
Date

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